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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,487	08/23/2001	Robert F. Rioux	BSCU-128/00US 027060-2694	1401

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PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/935,487	RIOUX ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8 and 17-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8 and 17-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is not seen how the coil providing radial strength to maintain an open passageway through a natural lumen of a patient further defines claim 1. In line 14 of claim 1, it is already understood that radial strength to maintain the lumen open is provided since it is recited in similar terminology.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17,18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. If there is only one winding spaced from each other, how can there be a distance of about 0.5mm separating windings along the length? Claim 17 recites it is located at the distal portion. If there is only **one** winding it must be central to both the distal and proximal ends of the coil segment such that it cannot be considered at a distal portion and then have the same spacing between windings.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard (WO 97/27898) in view of Lee et al. (5123917). Evard et al. illustrates (Fig. 2') a coil segment with a middle portion **14** spaced from the proximal and distal windings and has a diameter less than the proximal and distal ends. Evard et al. disclose a covering or what can be interpreted as "webbing" such that the entire device is encapsulated or *covered* by the covering, page 33, lines 8-13. It can be interpreted from the disclosure of Evard on page 14, lines 22-25 that these coverings inhibit ingrowth of body tissue. Evard also discloses the coil can be a biocompatible wire made from steel or nickel titanium, page 34, lines1-3. The Examiner is also interpreting the limitation "webbing between the windings" to be present in the Evard device since the covering is over the windings, it can be considered between the windings. The stent device is capable of being positioned coaxially within the body lumen of a patient. The apparatus is capable of use and of sufficient strength to maintain the urethra open. Evard does disclose the length of the device can vary and is chosen to accommodate the need of the patient (page 19, lines 7-9, page 33, lines 35-37, page 40, lines 1-7), thus the coil segment can be configured to extend from near the opening of a patient's bladder through the urethra and terminate before the sphincter. However, Evard fails to disclose the distance between the windings to be at least about 0.5mm or that the

webbing or covering is inner and outer layers adhered together or the specific cross sectional area of the wire. Lee et al. teach a spacing between coils to be greater than 0.5mm (col. 5, lines 41-43) when positioned in the vessel. Lee et al. also teach (Figs. 3,4) a stent with coils **30** having both inner **10** and outer **20** layers of polymer encapsulate the coil body for physical barrier of blood, col. 3, lines 65-68. Lee also teaches to have the polymer layers adhered together, col. 5 lines 29,30. Lee additionally teaches a cross-sectional area of the wire that falls within the claimed range of 0.0079mm^2 to 7.1 mm^2 (col. 5, lines 59-61). It would have been obvious to one of ordinary skill in the art to bond or adhere inner and outer polymer layers on the coil stent and space coil windings at least about 0.5mm and use a wire having a cross-sectional area within 0.0079mm^2 to 7.1 mm^2 as taught Lee et al. for the device of Evard such that the desired spacing between windings for flexibility can be established within the layers.

Claims 6,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Lee et al. '917 as applied to claim 1 and further in view of Yachia et al. (5246445). Evard as modified by Lee et al. is explained supra. However, Evard in view of Lee do not disclose the distal and proximal portions of the coil segment include hooks. Yachia et al. teach (Fig. 1a) a stent with hooks **3** at both the proximal and distal ends of the coil body for connection to a delivery system, col. 6, lines 13-16. It would have been obvious to one of ordinary skill in the art to incorporate hooks at both proximal and distal ends of a stent as taught Yachia et al. in the device of Evard as modified by Lee et al. such that the vessel apparatus does not dislodge from the instrument used to implant it. The addition of the hooks enables the surgeon to

precisely place the vessel-opening device in its location without the apparatus being displaced during insertion.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Lee et al. '917 as applied to claim 1 and further in view of Hachtman et al. (5645559). Evard as modified by Lee et al. is explained supra. Evard does disclose the polymer is elastomeric (page 33, lines 5,6) and that silicone layers can be placed on stents, page 17, lines 21-24. However, Evard in view of Lee do not disclose the polymer being a *low durometer* silicone within the range of 0-60D. Hachtman et al. teach that a silicone layer is placed on the stent to provide a barrier that prevents the growth of tissue through the stent and to support the flow of fluid through the lumen, col. 2, lines 14-18. Hachtman et al. also teach that low durometer silicone, such as 30D is placed on a stent, col. 4, lines 49-52. It would have been obvious to one of ordinary skill in the art to use a 30D silicone as taught by Hachtman et al. for the silicone on Evard's stent as modified by Lee et al. such that fluid flow is maintained through the lumen of the device while preventing tissue ingrowth.

Claims 17,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Lee et al. '917 as applied to claim 1 and further in view of Thorud et al. (6019779): Evard as modified by Lee et al. is explained above. However, Evard in view of Lee fail to explicitly disclose a longer coil such that there are multiple windings and spaces there between. Thorud et al. teach (Figs. 2,3) a coil device for a lumen having multiple windings with the distance between the spaced

windings being about 0.5mm, col. 5, lines 3-5. It would have been obvious to one of ordinary skill in the art to lengthen the coil device of Evard in view of Lee such that the spacing between windings is about 0.5mm with a winding located at the distal end as taught by Thorud et al. and provide a greater length stent for keeping a passageway open that has larger distance to span.

Response to Arguments

Applicant's arguments filed 10/26/07 have been fully considered but they are not persuasive. In response to applicant's argument that the Lee '917 device is used for something different than the Evard device, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both devices are used for maintaining fluid flow of vessels. Whether the two devices are intended to be placed entirely within a lumen or connect with a lumen is irrelevant because both are designed to maintain the fluid of lumens of a patient. Additionally, the teaching only provides how far to place support structure coils when keeping a lumen open.

Applicant also argues that the incorporation of a hook as disclosed by Yachia with Evard's device is not obvious since Applicants' allege there is no motivation to combine. As pointed out by the Examiner, Yachia teaches coil devices can include hooks such that the surgeon has the ability to manipulate the device in the lumen. To

further support the argument, connection apparatus as disclosed by Evard can be made with hooks, Sawada (6423087) teaches a hook to deliver such a device. Additionally, Berg (6451048) also teaches that hollow connectors can have hooks on them for fixation purposes. Thus, in response to Applicant's remarks that there is no teaching in the references to combine the features of the prior art, it should be noted that *Ex parte Smith* 83 USPQ2d 1509 states the KSR decision explains why no teaching is required to support a finding of obviousness. For example the combination of known features is obvious when it does nothing more than produce predictable results. In this case using hooks clearly provides an advantage of controlled delivery as taught by Yachia.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (8:30-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BRIAN E. PELLEGRINO
PRIMARY EXAMINER